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**TELECOPIER TRANSMISSION
COVER SHEET**

Date: September 18, 2006 Attorney Docket Number: 9013-56IP
Telecopier No.: 571-273-0459 Serial/Confirmation No.: 10/529,917
To: Office of PCT Legal Administration ATTN: Cynthia Kratz, Esq.
Company: U.S. Patent and Trademark Office
From: Alice M. Bonnen Return fax to: S. Abraham
Number of Pages (including cover sheet): 15

If there is a problem with this transmission, please call (919) 854-1400.
Our fax number is (919) 854-1401.

Comments:

Please see the attached request. This was the topic of a prior telephone call and is being faxed to you at your suggestion.

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International Division

Confidentiality Note

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THANK YOU.

SEP. 18. 2006 10:10AM

919-854-1401 MBS&S

NO. 3070 P. 2

PATENT

Attorney Docket No. 9013-56IP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Confirmation No.: 8053

In re: March

Application No.: 10/529,917

International filing date: October 2, 2003

For: *Bacteriophage Mediated Immunisation Against Hepatitis*

September 18, 2006

Via Facsimile: 571-273-0459
Attn: Cynthia Kratz, Esq.

Mail Stop PCT
Attn: Office of PCT Legal Administration
Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

**REQUEST FOR ENTRY OF SECOND PRELIMINARY AMENDMENT
UNDER 35 U.S.C. § 1.115**

Madam:

First Submission Under 35 U.S.C. § 371 Resulting in Serial No. 10/529,917

A U.S. National Entry application of PCT/GB03/004267 was filed by Express Mail No. EV 675779997 US on April 1, 2005. The Receiving Office stamped our return receipt postcard with the date April 1, 2005 and serial number 10/529,917 (Attachment A).

The transmittal form and fee worksheets are available in the PAIR Image File Wrapper for Serial No. 10/529,917 and are thus not included herewith.

Subsequent filings for Missing Requirements and an Information Disclosure Statement were made in due course and are part of the record for Serial No. 10/529,917.

Second Submission Under 35 U.S.C. § 371 Resulting in Serial No. 10/530,423

A second preliminary amendment was filed April 4, 2006 by Express Mail No. EV 675780006 US. Copies of the Transmittal Letter, Second Preliminary Amendment and our return receipt postcard are attached as **Attachment B**. The Transmittal Letter is clearly identified as a second or subsequent submission for PCT/GB03/004267. This second submission resulted in a second serial number being assigned to the national entry of PCT/GB03/004267. That serial number is 10/530,423.

Request for Refund of Duplicate Filing Fee

Deposit Account No. 50-0220 was charged the \$1,050.00 filing fee for Serial No. 10/530,423. A marked copy of the deposit account statement is attached (**Attachment C**).

Applicants request that the \$1050.00 filing fees charged to Serial No. 10/530,423 be refunded as a credit to Deposit Account 50-0220.

Request for Entry of Second Preliminary Amendment in Serial No. 10/529,917

Applicants respectfully request that the Second Preliminary Amendment, which resulted in Serial No. 10/530,423 be entered into the record for Serial Number 10/529,917.

It is respectfully submitted that the Second Preliminary Amendment meets the requirements of 37 CFR § 1.115 and request that it be entered into the record for Serial Number 10/529,917 as of the date of receipt by the USPTO, April 5, 2005, as evidenced by the date stamp on the return postcard (**Attachment B**).

Request for Correction of Application Data

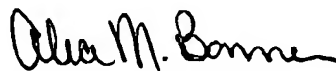
Applicants request that the application title be corrected in the Bibliographic Data on PAIR. Please change the word "Bacteriophage" to -Bacteriophage-.

Request for Filing Receipt and Notice of Acceptance

Applicants request that a Notice of Acceptance and Filing Receipt issue in due course for Serial No. 10/529,917, all requirements having been satisfied at the submission of Missing Requirements, received by the USPTO on October 11, 2005.

If the responsible attorney requires more information in order to act on these requests, she is invited and encouraged to contact the undersigned at the numbers given below.

Respectfully submitted,



Alice M. Bonnen
Registration No. 57,154
Attorney for Applicants

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428, Raleigh, NC 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401

CERTIFICATION OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the Office of PCT Administration, U.S. Patent and Trademark Office, on September 18, 2006.

Signature:  Date: Sept. 18, 2006
Typed Name of Person Signing Certificate: Sarah Abraham

Attachment A
Serial No. 10/529,917

MS:PLT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

7msibcl

Date: 4-1-05
Doc. No. 9013-56-TP
Serial No. To Be Assigned
Inventor: March

Sir: Kindly acknowledge receipt of the accompanying items listed below
by placing your receiving stamp hereon and return mailing:

☒ Application Transmittal and:

☐ Specification pages _____
☐ No. of Claims _____
☐ Declaration & POA _____
☐ Assignment and Fee _____
☐ Small Entity Statement _____
☐ Formal Drawings/ _____ sheets
☐ Associate Power of Attorney _____
☒ Exp. Mail _____ 1st Class Mail _____

☒ Check \$ 1,050.00
☐ IDS & PTO-1449 & _____ refs.
☐ Amendment & Amend. Transmittal
☒ Preliminary Amendment
☐ Issue Fee
☐ Brief
☐ Appeal
☐ Submittal of Priority Doc.

☒ Other:

FFT Publication WO 2004/030694 A1
JCO3 REC d PCI/PTO 01 APR 2009

10/529917

Respectfully submitted,
MYERS BIGEL SIBLEY & SAJOVEC, P.A.
Attorneys for Applicant

Attachment B
Serial No. 10/529,917

MS: PCT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FMS/BLK

Date: 4-5-05

Doc. No. 9013-SLTP

Serial No. 10/529,917

Inventor: March

Sir: Kindly acknowledge receipt of the accompanying items listed below
by placing your receiving stamp hereon and return mailing:

Application Transmittal and:

Check \$

Specification pages

IDS & PTO-1449 & refs.

No. of Claims

Amendment & Amend. Transmittal

Declaration & POA

Preliminary Amendment (2nd)

Assignment and Fee

Issue Fee

Small Entity Statement

Brief

Formal Drawings/ sheets

Appeal

Associate Power of Attorney

Submittal of Priority Doc.

Exp. Mail

Class Mail

Other:

JCO3 Rec'd PCT/PTO 05 APR 2005

Respectfully submitted,
MYERS BIGEL SIBLEY & SAJOVEC, P.A.
Attorneys for Applicant

EV675780006US



EV 675780006 US

Mailing Label
Label 11-F, April 2004



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Date Accepted	Scheduled Date of Delivery Month Day	Return Receipt Fee \$
Mo. Day Year	Scheduled Time of Delivery Month Day	COD Fee \$ Insurance Fee \$
Time Accepted <input type="checkbox"/> AM <input type="checkbox"/> PM	<input type="checkbox"/> noon <input type="checkbox"/> 3 PM	Total Postage & Fees \$
Flat Rate <input type="checkbox"/> or Weight	<input type="checkbox"/> 2nd Day <input type="checkbox"/> 3rd Day	Acceptance Emp. Initials
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Mo. Day		

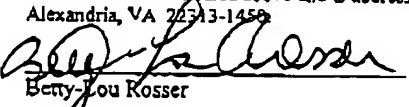
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1487A 2000 F:02 T:

Form PTO-1390 (REV. 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	A. RNEY DOCKET NUMBER 9013-561P
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) To Be Assigned
INTERNATIONAL APPLICATION NO. PCT/GB03/004267	INTERNATIONAL FILING DATE October 2, 2003	PRIORITY DATE CLAIMED October 2, 2002	
TITLE OF INVENTION Bacteriophage-Mediated Immunisation Against Hepatitis			
APPLICANT(S) FOR DO/EO/US John March			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (22) indicated below. 4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4) 7. <input type="checkbox"/> Amendments to the claims of the International Application Under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report Under PCT Article 36 (35 U.S.C. 371(c)(5)). 			
Items 11 to 21 below concern document(s) or information included:			
<ol style="list-style-type: none"> 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A FIRST preliminary amendment. 14. <input checked="" type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 16. <input type="checkbox"/> A substitute specification. 17. <input type="checkbox"/> A change of power of attorney and/or address letter. 18. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825. 19. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 20. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4) 21. <input type="checkbox"/> Other items or information: 			

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) To Be Assigned		INTERNATIONAL APPLICATION NO. PCT/GB03/004267		ATTORNEY DOCKET NO. 9013-567P		
21. The following fees are submitted: a) Basic national fee..... \$300.00 b) Examination fee..... \$200.00 c) Search fee..... \$500.00 TOTAL OF ABOVE CALCULATIONS = \$1000.00				CALCULATIONS		
				300.00		
				200.00		
				500.00		
				1,000.00		
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.						
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE			
-100+	-50+		X \$250.00			
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).			\$			
CLAIMS		NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims		21- 20 =	1	x \$ 50.00	\$50.00	
Independent Claims		2- 3 =	0	x \$200.00	\$0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$360.00	\$0.00	
TOTAL OF ABOVE CALCULATIONS =					\$1,050.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2						
SUBTOTAL =					\$1,050.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).						
TOTAL NATIONAL FEE =					\$1,050.00	
Fee for Recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +						
TOTAL FEES PREVIOUSLY PAID =					\$1,050.00	
					Amount to be refunded:	\$
					charged:	\$
a. <input type="checkbox"/> A check in the amount of \$0.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. 50-0220 in the amount of \$_____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0220. A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.						
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.						
SEND ALL CORRESPONDENCE TO: F. Michael Sajovec Myers Bigel Sibley & Sajovec, P.A. P. O. Box 37428 Raleigh, North Carolina 27627 Telephone: (919) 854-1400 Facsimile: (919) 854-1401 Customer No. 20792						
F. Michael Sajovec, Reg. No. 31,793 Date: <u>April 5, 2005</u>						
CERTIFICATE OF EXPRESS MAILING Express Mail Label No. EV675780006US Date of Deposit: April 5, 2005 I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop PCT, P.O. Box 1450, Alexandria, VA 22313-1450.						
 Betty Lou Rosser						

Attorney's Docket No. 9013-56IP

PATENT

IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

In re: March

International Appl. No.: PCT/GB03/004267

Application Serial No. To be assigned

International Filing Date: October 2, 2003

Filed: Concurrently herewith

For: *BACTERIOPHAGE-MEDLATED IMMUNISATION AGAINST HEPATITIS*

Date: April 5, 2005

Mail Stop PCT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SECOND PRELIMINARY AMENDMENT

Sir:

Prior to the examination of the above application, please amend the above-identified application as follows. If any extension of time for the accompanying response or submission is required, Applicant requests that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to Deposit Account No. 50-0220.

In re: March
Application Serial No. To be assigned
Filed: Concurrently herewith
Page 2

International Appl. No.: PCT/GB03/004267
International Filing Date: October 2, 2003

IN THE CLAIMS:

1. (Original) A hepatitis vaccine formulation comprising a bacteriophage particle the surface of which is unmodified and a pharmaceutically acceptable carrier therefor, the bacteriophage particle comprising an exogenous nucleic acid molecule encoding a hepatitis virus polypeptide which is capable of expression and presentation on the surface of an antigen presenting cell of an organism, such that an immune response to said polypeptide is raised in the organism.
2. (Original) The hepatitis vaccine according to Claim 1 for use in vaccinating against hepatitis types A, B, C, D, and/or E.
3. (Previously Presented) The hepatitis vaccine according to Claim 1 wherein the antigen expressed and presented on the surface of the antigen presenting cell is a hepatitis surface antigen.
4. (Previously Presented) The hepatitis vaccine according to Claim 2 wherein the bacteriophage has been engineered to express more than one hepatitis antigen.
5. (Original) A vaccine formulation comprising greater than 10^9 bacteriophage particles, the surface of each particle being unmodified, and a pharmaceutically acceptable carrier therefor, the bacteriophage particle comprising an exogenous nucleic acid molecule encoding a hepatitis virus polypeptide which is capable of expression and presentation on the surface of an antigen presenting cell of an organism, such that an immune response to said polypeptide is raised in the organism.

In re: March
Application Serial No. To be assigned
Filed: Concurrently herewith
Page 3

International Appl. No.: PCT/GB03/004267
International Filing Date: October 2, 2003

6. (Previously Presented) The vaccine formulation according to Claim 5 which is capable of eliciting a humoral and/or cellular immune response.
7. (Original) The vaccine formulation according to claim 5 for use in vaccinating against a virus, bacterium, fungus, yeast, protozoan, helminth, insect or transmissible spongiform encephalopathy.
8. (Original) The vaccine formulation according to claim 5 for use in eliciting an immune response against a cancer cell by means of the expression of a cancer cell specific antigen.
9. (Previously Presented) The vaccine formulation according to Claim 5 wherein the bacteriophage comprises transcriptional and/or translational regulators to facilitate expression of the polypeptide.
10. (Original) The vaccine formulation according to claim 9 comprising a eukaryotic promoter, such as the CMV, SV40, thymidine kinase or RSV promoter.
11. (Original) The vaccine formulation according to claim 9 which comprises the exogenous nucleic acid under control of a constitutive promoter and a controllable promoter.
12. (Previously Presented) The vaccine formulation according to Claim 9 wherein the bacteriophage is lambda (λ), p1 phage, T phage, Mu, fd, M13 or a filamentous phage.

In re: March
Application Serial No. To be assigned
Filed: Concurrently herewith
Page 4

International Appl. No.: PCT/GB03/004267
International Filing Date: October 2, 2003

13. (Previously Presented) The vaccine formulation according to Claim 9 wherein the bacteriophage is capable of expressing single or multiple copies of a polypeptide or a plurality of polypeptides.

14. (Previously Presented) The vaccine formulation according to Claim 9 wherein the bacteriophage is abortive to lytic growth in the natural bacterial flora of the chosen mammalian host.

15. (Previously Presented) The vaccine formulation according to Claim 9 further comprising inhibitors of lysosomal/endosomal enzymic catabolism and/or nuclear localisation signals.

16. (Previously Presented) The vaccine formulation according to Claim 9 further comprising an amount of the polypeptide to be expressed by the bacteriophage.

17. (Previously Presented) The vaccine formulation according to Claim 9 wherein the bacteriophage has been modified to express the polypeptide on the surface of the phage particle.

18. (Previously Presented) The vaccine formulation according to Claim 9 wherein the exogenous nucleic acid also encodes a polypeptide capable of augmenting the immune response.

19. (Previously Presented) The vaccine formulation according to Claim 9 further comprising an adjuvant.

20. (Previously Presented) The vaccine formulation according to Claim 9 wherein the bacteriophage is associated with a vehicle.

SEP. 18. 2006 10:12AM

919-854-1401 MBS&S

NO. 3070 P. 12

In re: March
Application Serial No. To be assigned
Filed: Concurrently herewith
Page 5

International Appl. No.: PCT/GB03/004267
International Filing Date: October 2, 2003

21. (Previously Presented) The vaccine formulation according to Claim 9
for use in the prophylaxis and/or treatment of a disease in a human or animal.

22. (Cancelled)

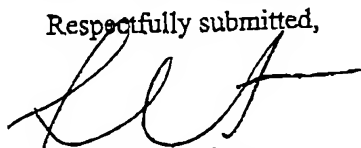
In re: March
Application Serial No. To be assigned
Filed: Concurrently herewith
Page 6

International Appl. No.: PCT/GB03/004267
International Filing Date: October 2, 2003

REMARKS

Applicants provide this second Preliminary Amendment to clarify the number of claims pending in this application for examination and for claim fee calculation purposes. Applicants respectfully request substantive examination on the merits.

Respectfully submitted,



F. Michael Sajovec
Registration No. 31,793

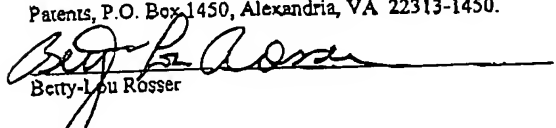
USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec
Post Office Box 37428
Raleigh, North Carolina 27627
Telephone: 919/854-1400
Facsimile: 919/854-1401

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number: EV675780006US

Date of Deposit: April 5, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Betty-Lou Rosser